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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF  
BIGAUD ET AL.  
APPLICATION NO: 10/581,068  
FILED: NOVEMBER 9, 2006  
FOR: BIOMARKERS FOR GRAFT REJECTION

Art Unit: 1634

Examiner: Kapushoc, Stephen Thomas

**MS: Amendment**  
Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

Sir:

This communication is in response to the Office Action of September 19, 2008. A one-month extension of time petition is included herewith. Reconsideration is respectfully requested.

Accordingly, Applicants elect the subject matter of Claim Group I (Claim(s) 1 and 2 in part as they require mRNA expression, and claims 6, 9-10, and 13-15) for further prosecution in this application. This election is made with traverse.

In addition, an election of a single species to which the claims shall be restricted is required. Applicants elect species AIF-1 (allograft inflammatory factor -1), which is the first gene listed in table 1. This election is also made with traverse.

Restriction between groups 1 and 2 is improper. In these two groups, the Examiner is restricting based on the mode of detection of the gene(s) of interest, said detection being via measuring either mRNA (group 1) or protein (group 2). Regardless of the mode of detection, the inventive concept between groups 1 and 2 is the same. The special technical feature that Applicant's invention contributes over the prior art is monitoring transplant rejection using the genes of Tables 1, 2 and 3. Applicant's have discovered that the genes of Tables 1, 2 and 3 are

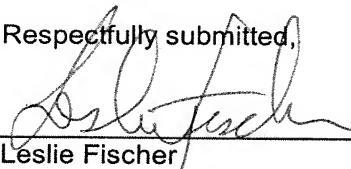
linked to the progression of transplant rejection, which feature is shared between groups 1 and 2, and which feature the Examiner has not identified in the art. The detecting modality one chooses to effect Applicant's inventions, e.g., detecting via a change in mRNA or protein, does not give rise to different inventions. The same may be said for groups 3 and 4. Accordingly, Applicants respectfully request withdrawal of the restriction between groups 1 and 2, and the restriction between groups 3 and 4.

The Examiner is also requiring election of a species (i.e., a gene from Table 1, 2 or 3). The Examiner has merely identified a gene from those tables as existing in the prior art. However, the special technical feature that contributes over the prior art is the discovery of the genes of Tables 1, 2 and 3 being linked to the progression of transplant rejection, which linkage is not disclosed in the prior art. Thus, the alternatives from Tables 1, 2 and 3 have the same or corresponding technical feature that define a contribution over the prior art.

Markush practice for PCT unity of invention requires: A) a common property/activity and B) (i) a common structure OR (ii) that the alternatives belong to a recognized class of chemical compounds in the art. The common property of requirement is satisfied, as all genes identified in Tables 1-3 share the property of being differentially regulated during transplant rejection. Moreover, the components in Tables 1-3 are all nucleic acids, and as such belong to a recognized class of chemical compounds (e.g., polynucleotides). Accordingly, unity of invention exists between the genes in Tables 1-3, and the requirement for election of species is improper. Accordingly, Applicants respectfully request withdrawal of the requirement to elect a single gene from Tables 1-3.

An early favorable action on the merits is respectfully requested.

Respectfully submitted,

  
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Date: 10/17/08